

**REMARKS**

Claims 1-21 are pending. Claims 4 and 6 have been rejected and claims 1-3, 5 and 7-20 are withdrawn from consideration. No new matter has been added by way of the present amendments. For instance, the specification has been updated to reflect the current status of the parent application. Additionally, claim 4 has been amended to recite "[a]n isolated" nucleic acid according to previous limitation (d). Additionally, the word "originated" has been replaced with "originating" and the word "Dalton" has been placed in the claims as requested by the Examiner. Claim 6 has been amended to be placed into independent format and new claim 21 has been added as supported by the present specification at page 44, lines 7-17. Accordingly, no new matter has been added.

In view of the following remarks Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

**Objections to the Claims**

The Examiner has objected to claim 4 asserting that it should read only on a nucleic acid encoding the fungal antigen comprising SEQ ID NO: 2 and having a molecular weight of 25,000 Daltons. Applicants submit that claim 4 has been amended to recite this subject matter.

The Examiner has objected to claim 6 asserting that it is of improper dependent form. Applicants traverse and submit that claim 6 has been amended so as to be independent format.

The Examiner has rejected the phrase "a nucleic acid encoding a polypeptide" in claim 6 asserting that independent claim 4 is limited to a nucleic acid encoding a single antigen. Applicants submit that claim 6 has been amended to recite "a nucleic acid encoding a fungal antigen".

The Examiner has suggested amending claim 4, line 5 to change "originated" with "originating". Applicants traverse and submit that this suggested amendment has been adopted.

Lastly, the Examiner has suggested that claim 4, line 8 be amended to insert the word "Daltons" after "25,000". Applicants traverse and submit that this suggested amendment has been adopted.

In summary, Applicants traverse each of the Examiner's outstanding objections and submit that they have been rendered moot by the present amendments. Reconsideration and withdrawal thereof are respectfully requested.

**Issues Under 35 U.S.C. §101**

The Examiner has rejected claims 4 and 6 under 35 U.S.C. §101 asserting that these claims are directed to "non-statutory" subject matter. Applicants traverse and submit that these claims have been amended to recite an "isolated" nucleic acid. Accordingly, this

rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

**Issues Under 35 U.S.C. §112, second paragraph**

The Examiner has rejected claims 4 and 6 under 35 U.S.C. §112, second paragraph for the reasons recited at pages 5 and 6 of the outstanding Office Action. Applicants respectfully traverse these rejections.

First, the Examiner asserts that the recitation of "vaccine activity or allergen activity" in claims 4 and 6 is indefinite. Applicants respectfully disagree. The present specification, for instance at page 36, line 22 to page 37, line 7, fully defines these terms. Accordingly, one of ordinary skill in the art would have no problem ascertaining the metes and bounds of these terms. Accordingly, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Second, the Examiner has rejected claim 6 for the recitation of "capable of". Applicants traverse and submit that claim 6 has been amended to avoid this rejection by definitively stating that the nucleic acid "hybridizes to" a particular nucleic acid. Thus, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Issues Under 35 U.S.C. §102(b)

The Examiner has rejected claim 6 under 35 U.S.C. §102(b) as being anticipated by Shen et al., 1989, (Clinical and Experimental Allergy, Vol. 19: 191-196).

The Examiner has also rejected claim 4 under 35 U.S.C. §102(b) as being anticipated by Ishiguro et al., 1992, (Infection and Immunity, Vol. 60: 1550-1557).

Applicants respectfully traverse each of these rejections.

The Examiner states that the sonicated preparation disclosed by Shen inherently comprises a nucleic acid encoding a peptide having an allergen activity since the sonicated preparation contains allergenic antigens that are encoded by a nucleic acid. Further, the Examiner asserts that the disclosed crude extract by Ishiguro inherently comprises a nucleic acid encoding an antigenic protein having allergen activity from *Candida albicans*, since the protein has a molecular weight of 25kD formulated by SDS-PAGE. Applicants respectfully disagree with the Examiner's characterization of these references.

Applicants submit that the cited references of Shen and Ishiguro fail to suggest or disclose an isolated nucleic acid as defined in the present claims. Applicants recognize that in order for a reference to inherently anticipate a claim, it is not necessary that one skilled in the art would appreciate that the

prior art possesses the claimed characteristics. In this regard, it has been stated:

Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. ... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. *Atlas Powder Co. v. Hanex Products, Inc.*, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

However, a theory of inherency must be supported by facts and/or technical reasoning that reasonably support a determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy*, 17 USPQ2d 1461 (BPAI 1990) (emphasis added). In order for prior art to anticipate a claimed compound on the ground it is inherently produced in a prior art process, the inherency must be certain. *Glaxo, Inc. v. Novopharm Ltd.*, (EDNC 1993) 830 F. Supp 871, 29 USPQ2d 1126; *Ex parte Cyba* (POBA 1966) 155 USPQ 756; *Ex parte McQueen* (POBA 1958) 123 USPQ 37. The fact that a prior art article may inherently have the characteristics of the claimed product is not sufficient. *Ex parte Skinner* (BPAI 1986) 2 USPQ2d 1788. Inherency must be a necessary result and not merely a possible result. *In re Oelrich* (CCPA 1981) 666 F2d 578, 212 USPQ 323; *Ex parte Keith et al.* (POBA 1966) 154 USPQ 320.

However, the inherency asserted by the Examiner is not a certainty based upon the prior art. It is merely speculation.

Although antigen components of 25kD are disclosed in Table 1 of Ishiguro, its common reaction is extremely low in comparison with antigens 175, 125, 46, 43 and 37kD disclosed as the most common IgE-binding antigen components. Further, as shown in Table 1 of Shen, the component of the 25kD as allergenic components is not shown. Further, protein bands of 44, 41, 40, 36 and 33kD are strongly stained. Thus, when each of these references is reviewed it is impossible to conclude with any certainty that an isolated nucleic acid encoding a fungal antigen comprising an antigenic 25kD protein having a vaccine activity as disclosed in the present application is present. The Examiner simply has not provided sufficient facts or technical reasoning which reasonably supported determination that the allegedly inherent characteristics of the present claims necessarily flow from the teachings of the prior art. These rejections are therefore improper and should be withdrawn.

Further, Applicants point out that the fungal antigen *per se* encoded by the nucleic acid of claim 4, is already allowed in claim 3 of parent application, U.S. Patent 6,333,164 B1. Accordingly, the nucleic acid encoding fungal antigen should also be allowable. Reconsideration and withdrawal of this rejection is again further requested.